

Three steps to boost your GMM drug clinical trial recruitment

BY DR SHURENE BISHOP SIMON

The pharmaceutical industry has seen a significant increase recently in the design and trial of drugs based on genetically modified microorganisms (GMM). This trend is likely to continue as new genetic engineering technologies become available, meaning more clinical trials and demand for patient recruitment.

The greater the pool of suitable participants recruited, the greater the inflow and quality of data to test a product's efficacy. This is particularly important when developing treatments for rare medical conditions.

It is no secret that hospitals and convalescent settings are the best place to recruit patients, but how to optimise recruitment into GMM drug trials? Here are three essential steps to success.

1) Set expectations

In my experience, when hospital stakeholders are not informed of all the necessary steps at an early stage in discussions, drug companies have been unable to increase recruitment. Not all relevant stakeholders will be versed in the

regulatory and biosafety requirements of clinical trials.

Surprises in the process have resulted in hospitals pulling out of trials. Clinicians care about their patients and want to go the extra mile to help them, so give them specific information about what is going to happen from the start. An easy-to-read document will help convince prospective trial sites and give clinicians confidence. This approach will go a long way to convincing your prospective trial sites to take part in your study and to have confidence in you.

2) Hire an expert biosafety consultant
Reassure the hospital team that an expert is at hand to help them seamlessly navigate the trial process. Getting on board with your trial will impact on their limited time, so you need their buy-in. Ask them to visualise themselves in the back seat of your Bentley (other cars are available), with an expert biosafety consultant in the driver's seat. The 'driver' takes the stress out of the process by managing the stages, paperwork, and critical liaisons, allowing the hospital staff to simply enjoy the ride.

3) Flatten the speed bumps

Empower the biosafety consultant to chart the way. Too often, success is hindered by having to rely on third-party consent for every action. Progress slows if every biosafety-related piece of work goes through the contract research organisation or pharmaceutical company for approval. This can affect the host's decision to stay on board. To avoid this, arrange a scope of work with your biosafety consultant that is reasonably unrestrictive, whilst producing the desired effect. The consultant will liaise with regulators, inspect premises, ensure compliance and co-ordinate a local committee as required.

These steps will improve your chances of increasing clinical trial recruitment, because you have approached the tasks at hand from the clinical site's workforce's perspective.

If you want to increase trial recruitment, Dr Shurene Bishop Simon is an expert biosafety consultant with extensive experience in facilitating GMM clinical trials.

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